Learn how **FENTORA** (fentanyl buccal tablet) CII may help you with breakthrough pain in cancer\(^1,2\)

**FENTORA** is a prescription medicine that contains fentanyl and is used to manage breakthrough pain in adults with cancer who are already routinely taking other opioid pain medicines around-the-clock for cancer pain. **FENTORA** is only available through the TIRF REMS Access program.

### Copay and reimbursement, simplified

**FENTORA** provides relief that generally matches the pattern of breakthrough pain in opioid-tolerant adults with cancer.\(^1,2\)

**FENTORA** is an oral tablet placed inside your mouth to dissolve.\(^2\)

**IMPORTANT SAFETY INFORMATION**

**IMPORTANT:**

- Do not use **FENTORA** unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant. Keep **FENTORA** in a safe place away from children.
- Get emergency help IMMEDIATELY if:
  - A child takes **FENTORA**. **FENTORA** can cause an overdose and death in any child who takes it
  - An adult who has not been prescribed **FENTORA** uses it
  - An adult who is not already taking opioids around-the-clock uses **FENTORA**
- These are medical emergencies that can cause death. If possible, try to remove **FENTORA** from the mouth.

*In accordance with the [Terms and Limitations]*

What important information should I know about **FENTORA**?

**FENTORA** can cause life-threatening breathing problems.

- **Use **FENTORA** exactly as prescribed by your healthcare provider**
  - **Do NOT** use more than 2 doses of **FENTORA** for each episode of breakthrough cancer pain
  - **Wait at least 4 hours** before treating a new episode of breakthrough cancer pain with **FENTORA**
- **Do not switch from **FENTORA** to other medicines that contain fentanyl or change your **FENTORA** dose without talking with your healthcare provider**
- **Never give **FENTORA** to anyone else**, even if they have the same symptoms you have. It may harm them or even cause death and is against the law. Keep **FENTORA** in a safe place

**FENTORA** is available only through a program called the Transmucosal Immediate-Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access program. To receive **FENTORA**, you must talk to your healthcare provider about the benefits and risks of **FENTORA**, agree to all of the instructions, and sign the Patient-Prescriber Agreement Form.

**Who should not use **FENTORA**?**

**Do not use **FENTORA**:**
FENTORA® (fentanyl buccal tablet) CII is a prescription medicine used to manage breakthrough cancer pain in adults with cancer who are already routinely taking other opioid pain medicines.

What should I tell my healthcare provider before using FENTORA?

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening side effects when taken with FENTORA.

- Do not take any medicine while using FENTORA until you have talked to your healthcare provider. Your healthcare provider will tell you if it is okay to take other medicines while you are using FENTORA.
- Be very careful about taking other medicines that may make you sleepy, such as other pain medicines, antidepressant medicines, sleeping pills, anti-anxiety medicines, antihistamines, or tranquilizers.

What should I avoid while using FENTORA?

- Do not drive, operate heavy machinery, or do other dangerous activities until you and your healthcare provider know how FENTORA affects you.
- Do not drink alcohol while using FENTORA. It can increase the chance of dangerous side effects.

What are possible side effects of FENTORA?

FENTORA can cause serious side effects, including:

1. Breathing problems that can become life-threatening.
   - Stop taking FENTORA and call your healthcare provider or get emergency medical help IMMEDIATELY if you:
     - Have trouble breathing
     - Have drowsiness with slowed breathing
     - Have slow, shallow breathing (little chest movement with breathing)
     - Feel faint, very dizzy, confused, or have unusual symptoms

These symptoms can be a sign that you have taken too much FENTORA or the dose is too high for you. These symptoms may lead to serious problems or death if not treated right away.

2. Decreased blood pressure. This can make you feel dizzy or lightheaded when you stand up.

3. Physical dependence. Do not stop taking FENTORA or taking any other opioid without talking to your healthcare provider. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependency is not the same as drug addiction.

4. A chance of abuse or addiction. This chance is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or have a history of mental health problems.

5. Pain, irritation, or sores at the application site (on your gum, on the inside of your cheek, or under your tongue).

The most common side effects of FENTORA are:

- Nausea
- Vomiting
- Dizziness
- Low red blood cell count
- Tiredness
- Swelling of the arms, hands, legs and feet
- Headache

Constipation is a very common side effect of opioid pain medicines including FENTORA and is unlikely to go away without treatment. Talk to your healthcare provider about prevention or treatment of constipation while taking FENTORA.

Talk to your healthcare provider if you have any side effects.

These are not all the possible side effects of FENTORA. For more information, ask your healthcare provider or pharmacist or call 1-800-896-5855.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, call 1-800-FDA-1088, or fax to 1-800-FDA-0178.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please see the Medication Guide located at the end of the Full Prescribing Information.